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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/663,272	11/25/96	HARRISON L	10308

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/663,272	Applicant(s) Harrison et al
	Examiner F. Pierre VanderVegt	Group Art Unit 1644

☒ Responsive to communication(s) filed on *8/20/98 and 11/30/98*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *2-37* ~~is~~/are pending in the application.

Of the above, claim(s) *8-29* ~~is~~/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *2-7, 30-33, and 35-37* ~~is~~/are rejected.

☒ Claim(s) *34* is/~~are~~ objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a 371 of PCT/AU96/00085.

Claim 1 has been canceled. New claim 37 has been added.

Claims 2-37 are currently pending in this application.

Election/Restriction

1. This application contains claims 8-29, which are drawn to an invention nonelected with traverse in Paper No. 7½, filed September 8, 1997. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 2-7 and 30-37 are the subject of examination in the present Office Action.

2. In view of the amendments filed August 20 and November 30, 1998, only the following rejections are maintained.

It is duly noted that new claim 37 has been entered as a replacement for claim 1. Accordingly, rejections and arguments previously directed towards claim 1 are now being applied to claim 37.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the Applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the Applicant for patent.

3. Claims 37, 2-5 and 7 stand rejected under 35 U.S.C. 102(a & e) as being anticipated by U.S. Patent No. 5,473,049 to Obermeier et al (A on form PTO-892, of record).

The '049 patent teaches recombinant proinsulin peptides which comprise the sequence (claimed as "X_2" in the instant application as a segment of 10-50 contiguous amino acid residues) "FFYTPKTRREAED" and further comprising flanking sequences which comprise no more than 5 amino acids residues (SEQ ID NOS: 4-7 in particular). Applicant is reminded that the term "comprising" recited in claims 37 and 7 is open-ended. It would open up the sequences to include other residues up to and including intact proteins comprising said sequences. Applicant is further reminded that a composition is a composition irrespective of what its intended use is (see *In re Tuominen*, 213 USPQ 89 (CCPA 1982)). The claimed recitation of intended use as a modifier of T cell function does not carry patentable weight per se. The claimed terms merely set forth a property inherent in an otherwise old proinsulin composition. The prior art teaching anticipates the claimed invention.

Applicant's arguments filed August 20, 1998 have been fully considered but they are not persuasive.

Applicant has attempted to differentiate the claimed invention from the teachings of the prior art by amending the claimed length in base claim 37 of X_2 from the original "10 to 100" amino acids to a length of "10 to 50" and by amending X_1 and X_2 [sic, presumed to mean X3] to be further limited by the recitation of "then no more than 5 contiguous amino acid residues are derived from human proinsulin or GAD65" in lines 13-14 of the claim. Claim 7 has not been substantially amended. Applicant contends that said amendment distinguishes the instant invention from the peptide of the prior art, but this is not the case. The new matter which has been introduced into the claim not withstanding (addressed infra in paragraph 8), Applicant is again reminded that the term "comprising" recited in claims 37 and 7 is open-ended. It would open up the sequences to include other residues up to and including intact proteins comprising said sequences. While X1 and X2 within the structure of the compound may not themselves consist of no more than 5 contiguous amino acid residues derived from human proinsulin or GAD65, $X_1X_2X_3$ is a formula claimed as being comprised in a recombinant or synthetic peptide. In order to narrow the claim in a manner which excludes N- and C- terminal extension of the recited sequences, it is suggested that the recitation of "comprising" in claim 1 and in claim 7 be

replaced by --consisting of--. However, it should also be noted that claim 1, using the foregoing closed terminology, would still encompass SEQ ID NO:7 taught by the '049 patent, as the length of that sequence is less than the 60 and more than the 10 amino acid residues which would be the limits of the instantly claimed peptide if written using closed terminology.

4. Claims 37, 2-4, 6-7, 30-33 and 35-36 stand rejected under 35 U.S.C. 102(a & e) as being anticipated by WO 92/20811, Zymogenetics et al (1C on form PTO-1449, of record).

The '811 PCT document teaches recombinant GAD peptides which comprise the sequence (claimed as "X_2" in the instant application as a segment of 10-50 contiguous amino acid residues) "FWYIPPSLRTLED" and further comprising flanking sequences which comprise no more than 5 amino acids residues (Fig. 2a-2e in particular). Applicant is reminded that the term "comprising" recited in claims 37 and 7 is open-ended. It would open up the sequences to include other residues up to and including intact proteins comprising said sequences. Applicant is further reminded that a composition is a composition irrespective of what its intended use is (see *In re Tuominen*, 213 USPQ 89 (CCPA 1982)). The '811 PCT document further teaches that the GAD peptides can be used as a pharmaceutical composition in a method of treatment to induce immunological tolerance or anergy in an individual predisposed or already mounting an immune response to GAD as an autoantigen (pages 20, line 29 to page 21, line 29 in particular). It is noteworthy that the process of inducing immunological tolerance includes within its scope the modification of responses to an antigen within both the T cell and B cell compartments. The prior art teaching anticipates the claimed invention.

Applicant has traversed this ground of rejection for the same reason applied to the rejection over the '049 patent, which has been addressed supra. Applicant further contends that the '811 document is not an applicable ground of rejection because the '811 PCT document allegedly does not teach peptides capable of interacting with T cells and modifying T cell function. The Examiner respectfully disagrees with this position. Applicant is invited to revisit the above-cited passage of the '811 PCT document (pages 20, line 29 to page 21, line 29 in particular) wherein it is taught that the GAD polypeptides can be used to induce immunological tolerance or nonresponsiveness (anergy) to GAD autoantigen. The teaching is not, as Applicant seems to suggest, directed toward autoantibodies. Immunological tolerance and anergy are phenomena well known by those in the art to occur in T cell populations reactive with a particular antigen.

Applicant is further invited to note claim 25 of the '811 PCT document in particular, in which T cell tolerance is specifically named.

5. Claims 37, 2-4, 6-7, 30-33 and 35-36 stand rejected under 35 U.S.C. 102(a & e) as being anticipated by U.S. Patent No. 5,674,978 to Tobin et al (B).

The '978 patent teaches recombinant GAD protein which comprises the sequence (claimed as "X_2" in the instant application) "FWYIPPSLRTLED" and further comprising flanking sequences which comprise 0 to 40 amino acids residues (Fig. 3a-3d in particular). Applicant is reminded that the term "comprising" recited in claims 37 and 7 is open-ended. It would open up the sequences to include other residues up to and including intact proteins comprising said sequences. Applicant is further reminded that a composition is a composition irrespective of what its intended use is (see *In re Tuominen*, 213 USPQ 89 (CCPA 1982)). The '978 patent further teaches the use of GAD protein as a pharmaceutical composition in a method of treatment to inactivate GAD reactive T cells and that this inactivation prevents long-term development of insulitis and diabetes in treated subjects (column 28, line 29 through column 29 in particular). The prior art teaching anticipates the claimed invention.

Applicant has traversed this ground of rejection by citing out of context the statement in the '978 patent that GAD peptides recognized by autoantibodies were different from those recognized by NOD GAD reactive T cells. It is noted by the Examiner that the NOD GAD reactive T cells to which the passage referred were those of Example 6 of the '978 patent. It should be pointed out that those "NOD GAD reactive T cells in Example 6" (col. 36, line 49) are the same cells referenced in the Office Action as those being inactivated by GAD peptide treatment (column 28, line 29 through column 29 in particular).

6. Claims 37, 2-4, 6-7, 30-33 and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaufman et al (U).

Kaufman et al teaches the use of an effective amount of human GAD peptide (Fig 1 in particular) to tolerize GAD reactive T cells, a modification of their function, in a subject (NOD mouse) and thereby block the development of T cell autoimmunity to other beta cell antigens and, subsequently, prevent the onset of insulitis and diabetes (Abstract in particular). Kaufman et al also teaches that this data would be applicable in immunotherapies for human IDDM patients (page 72 in particular). The method of Kaufman et al uses the full length human GAD peptide and, therefore, inherently comprises the amino acid segments and sequences particularly stated in the instant claims. The prior art teaching anticipates the claimed invention.

Applicant has not provided clear reasons for traversal of this ground of rejection, only summarizing the teachings of Kaufman et al.

7. **The following new grounds of rejection have been necessitated by Applicant's amendment.**

Claim Rejections - 35 U.S.C. § 112

8. Claims 2-7 and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification and claims as originally filed do not support the recitation of "then no more than 5 contiguous amino acid residues are derived from human proinsulin or GAD65" in lines 13-14 of claim 37 or the recitation of "chemical equivalent thereof" in line 15 of line 37. The specification and claims as originally filed disclose only "comprising from 0 to 40" (page 2, line 26 for example), "comprising from 0 to 15" (page 3, line 22 for example) amino acid residues as limitations for the length of X1 and X3 the peptides inclusive of particular amino acid sequences or derivatives thereof. Accordingly, the recitation introduces limitations into the claim which were not originally disclosed merely in an attempt to overcome the prior art of record and constitutes new matter which must be canceled in response to this Office Action.

9. Claims 2-7 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Base claim 37 is vague and indefinite in its recitation of segment X_2 as being both "0 to 40" amino acid residues in length in line 6 and "10 to 50" amino acid residues in length in line 8. This is an apparent typographical error and the claim should be corrected so that the recitation of "0 to 40" is instead applied to X_3.

Base claim 37 is vague and indefinite in its recitation of "residues then no more than five" in lines 12-13. The recitation is grammatically incorrect.

Claim 37 recites the limitation "or chemical equivalent thereof" in line 15. There is no antecedent basis for this limitation in the claim. Claim 37 earlier states only the peptides inclusive of particular amino acid sequences or derivatives thereof.

Conclusion

10. Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

13. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center

located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Monday through Friday from 8:00 am to 4:30 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

January 27, 1999
F. Pierre VanderVegt, Ph.D.
Patent Examiner
Art Unit 1644

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644